

JUL 24 2007

## 510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**The assigned 510(k) number is:** **K070767**

### **Applicant information:**

Date Prepared:	July 5, 2007
Name:	<b>Lapis Lazuli International NV</b>
Address	Damsluisweg 48 1332 ED Almer The Netherlands
Contact Person:	Mr. Mark Berkouwer Executive Officer
Phone number:	+31 (0) 36 547 6020
USA Consultant:	MedVice Consulting, Inc. Mr. Martin Dalsing
Phone number:	(970) 243-5490
Fax number:	(970) 243-5501
Email address:	marty@FDAapproval.com

### **Device Information:**

Device Classification:	Class II
Classification Number:	LPN 886.5928
Classification Name:	Accessories, soft lens products Soft (hydrophilic) contact lens care products

**Trade Name:** **EYE SEE™ Multipurpose, Contact Lens  
Solution**

## **Purpose of 510(k) Submission:**

Change in Directions for Use.

Change from 4 hour soak to a 10 Minute Express Disinfection, will be added to the Labeling and Directions for Use of Lapis Lazuli International's previously cleared 510(k) K051104~

Lapis Lazuli International NV Co. Ltd proposes to market and sell in United States interstate commerce, The **EYE SEE™ Multipurpose Contact Lens Solution with a new directions for use, the change from 4 hour soak to a 10 minute express disinfection.** Data supporting the 10-minute express disinfection is contained in this submission. The **EYE SEE™ Multipurpose Contact Lens Solution is the same solution as cleared in 510(k) K051104.**

## **Equivalent Devices:**

The **EYE SEE™ Multipurpose Contact Lens Solution** is substantially equivalent in terms of its actions and indications for use to the following predicate devices:

*PREDICATE DEVICES ~*

- The **EYE SEE™ Multipurpose Contact Lens Solution Manufactured by Lapis Lazuli International NV Co. Ltd.**
- The Aquify® Multi-Purpose Solution Manufactured by Ciba Vision®.

The **EYE SEE™ Multipurpose Contact Lens Solution** meets the guidelines set forth in FDA's May 1, 1997 Guidance for Industry; Premarket Notification 510(k) Guidance Document for Contact Lens Care Products.

## **Device Description:**

The **EYE SEE™ Multipurpose Contact Lens Solution** is a sterile, isotonic, buffered, solution containing boric acid, sodium chloride, Hydroxypropyl Methylcellulose (HPMC) as a lubricant, poloxamer 407 as a surfactant, disodium edetate as chelating agent, purified water and preserved with polyhexanide.

The **EYE SEE™ Multipurpose Contact Lens Solution** is a clear, colorless solution packaged in plastic bottles with controlled dropper tips.

## **Intended Use:**

**The EYE SEE™ Multipurpose Contact Lens Solution** is indicated for use in the daily cleaning, removal of protein deposits, rinsing, chemical (not heat) disinfection, and storage of soft (hydrophilic) contact lenses, as recommended by your eye care practitioner.

## **Pre-Clinical Performance Data:**

Data to demonstrate all indications: daily cleaning, rinsing, chemical (not heat) disinfecting, and storage of soft (hydrophilic) contact lenses, of the **EYE SEE™ Multipurpose, Contact Lens Solution** can be referenced in Lapis Lazuli 510(k) K051104 which shows all results are satisfactory. Permission to reference 510(k) K051104 is included in this 510(k).

**Chemistry Testing:** Reference 510(k) K051104 for all of the following chemistry testing:

1. Solution Compatibility
2. Cleaning Effectiveness
3. Stability
4. Enzymatic Cleaning Studies

**Microbial Testing:** Microbiological studies were conducted to demonstrate the microbial efficacy of **EYE SEE™ Multipurpose Contact Lens Solution for 10 Minute Express Disinfection**. This testing concluded that the product met primary stand-alone criteria.

Preservative Effectiveness with Re-challenge was conducted and met requirements for the Preservative Efficacy Test for Multi-Dos Preserved Contact Lens Care Products. This data can be referenced in 510(k) K051104.

**Toxicology Testing:** A series of Toxicology studies were conducted to demonstrate the safety of **EYE SEE™ Multipurpose Contact Lens Solution** and to demonstrate the safety of the packaging system. Results of the testing demonstrated that **EYE SEE™ Multipurpose Contact Lens Solution** is non-toxic and is a non-irritant. Reference 510(k) K051104

## **Clinical Study:**

A clinical study has been conducted, and results of this study can be referenced in the previously cleared 510(k) K051104.

### **Substantial Equivalence:**

The **EYE SEE™ Multipurpose, Contact Lens Solution** is substantially equivalent in terms of its actions and indications for use to the following predicate devices:

- The **EYE SEE™ Multipurpose, Contact Lens Solution Manufactured by Lapis Lazuli International NV Co. Ltd.**
- The Aquify® Multi-Purpose Solution Manufactured by Ciba Vision®.

### SUBSTANTIAL EQUIVALENCY CHART

<b>Substantial Equivalency</b>	<b>EYE SEE™ MULTIPURPOSE SOLUTION</b>		<b>The Aquify® Multi- Purpose Solution</b>
<b>Manufacture</b>	<b>Lapis Lazuli International</b>		<b>Ciba Vision®</b>
<b>INTENDED USE</b>	The EYE SEE Multipurpose Contact Lens Solution is indicated for use in the daily cleaning, removing protein deposits, rinsing, chemical (not-heat) disinfecting and storage of soft (hydrophilic) contact lenses, as recommended by your eye care practitioner.		The Aquify® Multi-Purpose Solution is indicated for the care of soft hydrophilic contact lenses. Use this product as recommended by our eye care practitioner to: Chemically (NOT HEAT) Disinfect, Clean, Rinse, Store, Remove Protein
<b>Preservative</b>	Polyhexanide 0.00015%,		Polyhexanide 0.00015%,
<b>Chelating Agent</b>	Disodium edetate		Disodium edetate
<b>Lens Care Regimen</b>	Rub and Rinse 10 Minute Express		Rub and Rinse 5 Minute Express
<b>Sterility Claim</b>	Sterile		Sterile



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Lapis Lazuli International, NV  
c/o Mr. Martin Dalsing  
Medvice Consulting, Inc.  
2214 Sanford Drive Suite B7  
Grand Junction, CO 81503

JUL 24 2007

Re: K070767

Trade/Device Name: EYE SEE™ Multipurpose Contact Lens Solution  
Regulation Number: 21 CFR 886.5928  
Regulation Name: Soft (hydrophilic) contact lens care products  
Regulatory Class: Class II  
Product Code: LPN  
Dated: July 5, 2007  
Received: July 12, 2007

Dear Mr. Dalsing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose  
and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K070767

**INDICATIONS FOR USE STATEMENT**

510(k) Number: K070767

Device Name: EYE SEE™ Multipurpose Contact Lens Solution

**INDICATIONS FOR USE:**

The EYE SEE™ Multipurpose Contact Lens Solution is indicated for use in the daily cleaning, removal of protein deposits, rinsing, chemical (not heat) disinfection, and storage of soft (hydrophilic) contact lenses, as recommended by your eye care practitioner.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marc Robley  
(Division Sign-Off)  
Division of Ophthalmic Ear,  
Nose and Throat Devices

510(k) Number K070767

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

or

Over-The-Counter Use X

(Optional Format 1-2-96)

